



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

October 26, 2005

FILE COPY

Mr. Thomas G. Williams
CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611

Dear Mr. Williams:

Your petition requesting that the Food and Drug Administration reclassify P990016 McCue CUBA Clinical Ultrasonic Bone Sonometry System was received by our office on 10/25/2005. It was assigned docket number 2005P-0431/CCP 1 and it was filed on 10/25/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0431

ACK 1